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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,272	02/06/2002	H. Andrew Strong	273012012500	1974

7590 05/17/2006

Kawai Lau
Morrison & Foerster LLP
Suite 500
3811 Valley Centre Drive
San Diego, CA 92130-2332

EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,272	STRONG ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on February 17, 2006 has been entered. Claims 1-2, 5-19 are pending.

Any rejection that is not addressed in this Office Action is considered withdrawn in view of the Amended claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5-12, 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. The phrase" an occult component of at least about 50% to 100% of the lesion" in claim 1 appears to be relative in nature, which renders the claim indefinite. The phrase " an occult component of at least about 50% to 100% of the lesion " is not defined by the claim, nor does the specification provide a standard for ascertaining the requisite degree of occult component of at least 50% -100 % of the lesion. It appears that such measurement is a function of the clinician's expertise and perception. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed invention, because assessing the claimed degree of occult component may vary from one clinician to the other.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-2, 5-12, 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over TAP Report 1 ("Photodynamic Therapy of Subfoveal Choroidal Neovascularization in Age-related Macular Degeneration with Verteporfin." Arch Ophtalmol.1999; 117:1329-1345) (the TAP Report).

The instant claims are directed to methods of treating an ocuult choroidal neovascular (CNV) lesion comprising administering photodynamic therapy to a subject having Occult CNV, wherein the subject is assessed as having either or both (a) a small lesion with a size less than about 4-5 disc areas or (b) poor visual acuity of less than about 65 letters prior to treatment and wherein the occult lesion comprise an occult component of at least about 50% to 100% of the lesion.

The TAP Report teaches the instantly claimed method. Tap Report teaches methods of administering verteporfin, a green porphyrin (which is also known as BPD-MA, see Reg Number 129497-78-5) to patients suffering from Occult CNV. (see page 1330 under the heading *Patient Selection*, last para.). Out of the 402 Patients in the Vertoporfin arm of the study, at least 305 patients had evidence of Occult CNV(see Table 2 at page 1334, last criteria under the category *Evidence of Occult CNV*). Further, out of the same 402 patients at least 199 patients had a visual acuity of less than 53 letters (see Table 2, Vertoporfin Arm, under the category *Visual Acuity* criteria). Thus, at

least about 100 patients who had received a photodynamic regimen of Verteporfin, had evidence of Occult CNV with visual acuity of less than 65.

Examiner also states that among the population in the Verteporfin Arm, 259 appear to have lesion size of less than 6 disc areas (see page 1335, table 2, under Vertoporfin Arm, Under *the Area of Lesion, MPS Disc Areas* criteria). Therefore, the population who showed Occult CNV in the TAP Report and further received verteporfin, are the same as the instantly claimed population. Said population received Verteprofin solution in amount of about 6 mg/m 2 (see abstract, also page 1332, at 1st col). Fifteen minutes after administration of the Verteprofin the CNV lesions were irradiated with a laser light for about 83 seconds in a light exposure of 50 J/CM2. (see col 1 page 1332). Accordingly, the limitations of claims 14-18 are met.

All method steps of the instantly claimed process are described for the population who showed Occult CNV prior to the therapy in the TAP Report Verteporfin Arm. Accordingly, the instantly claimed intended purpose is inherently achieved in the said population.

Applicant is also informed that the recitation of 45% efficacy of therapy in Occult CNV group, as recited in page 1338 is not a teaching away, because such conclusion does not mean that no patient has benefited from the methodology described in Vertopoifin Arm of the TAP Report. Rather, such percentage is only viewed as a comparison to the control group.

Examiner adds that the 33.1 % of the TAP Report's Verteporfin Arm included patients who had blood in their lesion which is viewed as the occult component of the

lesion. TAP Report only fails to explicitly state that the patients in the Verteporfin Arm of the study had an occult component of at least about 50% to 100% of the lesion.

Nevertheless, absent a showing of unexpected results or evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the method steps of TAP Report to treat patients with occult CNV lesion having an occult component of at least about 50% to 100% of the lesion, because as shown by the Report, one of ordinary skill in the art would have had a reasonable expectation of success to observe some degree of improvement in ocular condition of the patients suffering from said occult CNV.

4. Claims 1-2, 5-19 rejected under 35 U.S.C. 103(a) as being unpatentable over TAP Report in view of Zeimer US Patent 5,935,942.

The teachings of TAP report are described above. TAP report only fails to specifically describe attachment the use of a targeting ligand and the dosing of its photosensitizer per body weight of subjects.

Zeimer is used to describe the same process as in TAP report except that the photosensitzer is encapsulated or coupled with a targeting or tissue specific agent (see col 12, lines 28-50; col 14, lines 15-col 24). The process of Zeimer employs targeted liposomes (col 25-26) for patients having Occult CNV.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a targeting agent, such as an antibody, to the photosensitizer employed in TAP report, because as suggested by Zeimer, the ordinary skill in the art would have had a reasonable expectation of success in improving the clinical outcome

of such photodynamic therapy. Further, absent a showing of criticality, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the dosing ranges of the photosensitizer in TAP report by routine experimentation and express it based on the body weight of subjects.

Response to Arguments

5. Applicant's arguments filed on February 17, 2006 have been fully considered but they are not persuasive.

Relying on *Perricone v. Meicis Pharm. Corp*, 205 US. App LEXIS 28061 (hereinafter "*Perricone*") decided December 20, 2005, Applicant argues that occult CNV lesions of the instant claims, are not analogous to lesions generally described in TAP Report. (see Arguments at page 4-5). As the initial matter, *Perricone's* decision is not analogous with the instant case. In *Perricone* the prior art used for the anticipation arguments was directed to a composition and there was a brief description of its utility for skin. (*see* Courts explanation of Pereira at pages 4-5). However, the patented claims at issue (Perricone's claims) were directed to a specific method of use not specifically described in the prior art. (*Id.*) Moreover, the Court recognized substantial dissimilarities between the ingredients of the prior art composition and those of the patent at issue. (Id.at page 5).

Contrary to Applicant's analysis, the prior art employed for the instant rejection describes the same population of patients as the instant claims, undergoing the same process steps and receiving the same composition, as those of the instant claims.

Accordingly, all limitations of the instant claims are substantially described by TAP Report and Applicant's argument is not persuasive.

Conclusion

6. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER